Kansas Drug Utilization Review Newsletter

Health Information Designs, LLC **Summer 2014**

Welcome to the summer 2014 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

A Comparison of JNC7 and JNC8 Guidelines

In December 2013, the panel members appointed to the Eighth Joint National Committee (JNC8) released updated guidelines for the management of high blood pressure in adults. One important characteristic of the JNC8 guidelines is that they are not a comprehensive set of guidelines. They are merely an update to the JNC7 guidelines, which are more comprehensive and include definitions of hypertension, issues in blood pressure measurement, public health perspective, lifestyle modifications, and management of "special situations." The JNC8 guidelines focus almost entirely on drug therapy for hypertension.

One of the biggest differences to note in comparing the JNC7 and JNC8 guidelines is the transparency in JNC8 regarding its guideline-writing process. JNC7 recommendations are based on extrapolation from observational data, expert opinion, and data from randomized trials. The JNC8 guidelines were written using randomized trials and expert opinion, and state explicitly when the recommendation is based upon expert opinion.

In addition to the differences in what the guidelines cover and the methodology behind their development, the JNC8 guidelines also include updates to specific recommendations for drug therapy:

- A treatment threshold AND goal for patients age ≥60 is raised to 150/90 mmHg vs. the treatment threshold AND goal of 140/90 mmHg in JNC7.
- For patients with chronic kidney disease and patients with diabetes, the new JNC8 treatment threshold AND goal is 140/90 mmHg vs. the stricter 130/80 mmHg recommended by JNC7.
- JNC8 recognizes CCBs, ACE inhibitors, and ARBs along with thiazide-type diuretics as appropriate first-line drug therapy in nonblack patients with hypertension. (Beta-blockers are no longer recommended initially due to less protection against stroke.) JNC7 recommended a thiazide-type diuretic as initial drug therapy for hypertension (unless there was a compelling indication) with CCBs, ACE inhibitors, ARBs, and beta-blockers as alternatives.
- JNC8 recognizes thiazide-type diuretics and CCBs as the best first-line agents for treatment of hypertension in black patients.
- JNC8 recommends an ACE inhibitor or ARB for any patient with CKD and hypertension.
- If the blood pressure goal is not reached within one (1) month of treatment, JNC8 recommends increasing the dose of the initial drug or adding a second drug from one of the other recommended first-line drug classes. If the goal is still not reached, JNC8 recommends adding and titrating a third drug. If the goal is not reached with three (3) drugs, agents from other classes can be used.

The loosening of goals and treatment thresholds in the JNC8 guidelines should not be used to discontinue drug therapy in patients who have reached the original JNC7 goals. For example, if a patient has successfully reached a steady blood pressure of 135/85 mmHg, healthcare providers should continue the patient's effective regimen rather than converting to the less stringent JNC8 goals. Healthcare providers should also still utilize the thoroughness of the JNC7 guidelines—such as diet and exercise recommendations, management of "special situations," and other recommendations—to guide treatment.

In This Issue

Helpful Web Sites

KMAP Web Site
https://www.kmap-state-ks.us/

KDHE-DHCF Web Site
http://www.kdheks.gov/hcf/

KanCare Web Site
http://www.kancare.ks.gov/

Fee-For-Service (FFS) Helpful Numbers

Provider Customer Service
(Provider Use Only)
1-800-933-6593

Beneficiary Customer Service
1-800-766-9012

KMAP PA Help Desk
1-800-285-4978

Please send questions or comments regarding this newsletter to KSDURNewsletter@hidinc.com

New Cholesterol Guidelines: A Shift in Management

The recently published cholesterol treatment guidelines developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) have recommend substantial changes from the 2004 Third Adult Treatment Panel (ATP III) guidelines. The new guidelines abandon specific cholesterol treatment goals and instead focus on four high-risk groups that are most likely to benefit from statin therapy. The new guidelines also emphasize that overall risk of heart disease and stroke should be evaluated on an individual basis and recommend only using medications that have been proven to reduce atherosclerotic cardiovascular disease (ASCVD) risk.

To write the new guidelines, the expert panel focused heavily on high quality evidence from randomized controlled trials (RCTs) and systematic reviews of RCTs to create evidence-based recommendations, while the previous guidelines also included observational studies. The new guidelines argue that multiple RCTs have shown that ASCVD events are reduced by optimizing fixed doses of statin therapy rather than obtaining pre-specified LDL-C goals. The guideline panel concluded that there is insufficient evidence from RCTs that titration of LDL-C to specific targets further reduces coronary heart disease (CHD) or ASCVD beyond that achieved by simply giving a high-intensity statin. The guidelines acknowledge that treating to cholesterol targets could potentially result in overtreatment with non-statin therapies which have failed to show a reduction in secondary ASCVD and could result in adverse effects from the use of multiple medications.

The guidelines identified four high-risk populations that benefit from statin therapy and which therapy to initiate. These risk categories make it easier to identify individuals who are most likely benefit from treatment with a statin. Rather than focusing on LDL-C targets, the new guidelines take into consideration a patient's overall CV risk.

Risk Group	Recommended Therapy	Alternate Therapy
Adults with known ASCVD	High-intensity statin	Moderate-intensity statin (age >75 y or not a candidate for high-intensity)
Adults with LDL-C ≥ 190 mg/dL	High-intensity statin	Moderate-intensity statin (not a candidate for high-intensity)
Diabetics 40-75 years of age with LDL-C between 70-189 mg/dL	Moderate-intensity statin	High-intensity statin (estimated 10-y ASCVD risk ≥7.5%)
Patients 40-75 years of age with a 10 year ASCVD risk > 7.5% and LDL-C between 70-189 mg/dL	Moderate-to-high-intensity statin	

In patients >75 years old, it is reasonable to continue statin therapy in those who are tolerating it, as the recommendation for starting a lower dose is based on expert opinion and the potential for an increased risk of adverse effects and drug-drug interactions. In those who are intolerant to a high-intensity statin and/or who are receiving concomitant medications that can potentially increase risk of statin related adverse events, moderate intensity therapy is also recommended. There is good evidence to support a benefit from moderate intensity statins if a patient cannot tolerate the higher dose. The guidelines also acknowledge that non-statin drug therapy has not shown a reduction in ASCVD events in RCTs. The lack of evidence for other medications as well as the minimal safety concerns associated with statins is cited as reason for the major emphasis on statin therapy in the guidelines.

High- Moderate- and Low-Intensity Statin Therapy (from the ACC/AHA Guidelines)

High-Intensity Statins	Moderate-Intensity Statins	Low-Intensity Statins
Daily dose lowers LDL-C on average, by approximately ≥50%	Daily dose lowers LDL-C on average, by approximately 30% to <50%	Daily dose lowers LDL-C on average, by <30%
Atorvastatin 40-80mg Rosuvastatin 20-40mg	Atorvastatin 10-20mg Rosuvastatin 5-10mg Simvastatin 20-40mg Pravastatin 40-80mg Lovastatin 40mg Fluvastatin XL 80mg Fluvastatin 40mg BID Pitavastatin 2-4mg	Simvastatin 10mg Pravastatin 10-20mg Lovastatin 20mg Fluvastatin 20-40mg Pitavastatin 1mg

In conclusion, the recent ACC/AHA cholesterol guidelines have the potential to greatly simplify and improve care for those patients at a higher risk. Even with new guidelines, it remains essential that health care providers consider the risk benefit ratio for each individual patient.

Preferred Drug List

The Preferred Drug List (PDL) is maintained by KDHE-DHCF. Each MCO and KMAP follow the same PDL. Below is a list of current preferred agents. A complete list of both preferred and non-preferred agents may be found on the KDHE-DHCF Web site. The Preferred Drug List is typically updated on the first of each month; please visit the KDHE-DHCF Web site for the most recent version: http://www.kdheks.gov/hcf/pharmacy/pharmacy_druglist.html.

Allergy, Asthma, & COPD Agents

Anticholinergics for the Maintenance of COPD
Spiriva® (tiotropium)

Combination Products for Allergic Rhinitis
Dymista® (azelastine/fluticasone)

Short-Acting Beta$_2$-Agonists
AccuNeb® (albuterol)
ProAir HFA® (albuterol)
Proventil® (albuterol)
Ventolin® (albuterol)

Long-Acting Beta$_2$-Agonists
**Clinical PA may be required*
Foradil® (formoterol)
Serevent® (salmeterol)

Inhaled Long-Acting Beta$_2$-Agonists/Corticosteroids
Advair® (fluticasone/salmeterol)
Dulera® (formoterol/mometasone)
Symbicort® (budesonide/formeterol)

Inhaled Corticosteroids
Asmanex® (mometasone)
Flovent® (fluticasone)
Pulmicort Flexhaler® (budesonide)
Pulmicort Respules® (budesonide)
***≤6 years of age only**
QVAR® (beclomethasone)

Intranasal Corticosteroids
Flonase® (fluticasone)
Nasonex® (mometasone)
Qnasl® (beclomethasone)
Veramyst® (fluticasone)

Intranasal Antihistamines
Astelin® (azelastine)
Astepro® (azelastine)

Non-Sedating Antihistamines
Claritin® (loratadine)
Zyrtec® (cetirizine)

Ophthalmic Antihistamine/Mast Cell Stabilizer Combinations
Alaway® (ketotifen)
Pataday® (olopatadine)
Patanol® (olopatadine)
Refresh® (ketotifen)
Zaditor® (ketotifen)

Analgesics

COX-II Inhibitors
Celebrex® (celecoxib)

Long-Acting Opioids
MS Contin® (morphine sulfate ER)
OxyContin® (oxycodone SR)

Muscle Relaxants (Spasticity)
Lioresal® (baclofen)
Zanaflex® (tizanidine)
***tablets only**

Analgesics (continued)

Muscle Relaxants (Skeletal)
Flexeril® (cyclobenzaprine)
Parafon Forte DSC® (chlorzoxazone)
Robaxin® (methocarbamol)
Robaxin-750® (methocarbamol)
Robaxisal®

Ophthalmic NSAIDs
Acular® (ketorolac)
Acular LS® (ketorolac)
Acuvail® (ketorolac)
Ilevro® (nepafenac)
Nevanac® (nepafenac)
Ocufen® (flurbiprofen)
Voltaren® Ophthalmic (diclofenac)

Oral NSAIDs
Advil® (ibuprofen)
Aleve® (naproxen)
Anaprox® (naproxen)
Anaprox DS® (naproxen)
Ansaid® (flurbiprofen)
Cataflam® (diclofenac potassium)
Clinoril® (sulindac)
EC-Naprosyn® (naproxen)
Feldene® (piroxicam)
***branded products only**
Indocin® (indomethacin)
Lodine® (etodolac)
Mobic® (meloxicam)
Motrin® (ibuprofen)
Motrin IB® (ibuprofen)
Naprelan® (naproxen)
Naprosyn® (naproxen)
Orudis® (ketoprofen)
Orudis KT® (ketoprofen)
Oruvail® (ketoprofen)
Relafen® (nabumetone)
Tolectin DS® (tolmetin)
Tolectin 600® (tolmetin)
Toradol® (ketorolac)
***limited to a 5 day supply**
Voltaren® (diclofenac)
Voltaren® XR (diclofenac)

Topical NSAIDs
Flector Patch® (diclofenac)
Pennsaid® (diclofenac)

Triptans
Imitrex® (sumatriptan)
***tablets only**
Maxalt® (rizatropin)
Maxalt-MLT® (rizatropin)
Relpax® (eletriptan)

Antihyperlipidemics

Bile Acid Sequestrants
Colestid® (colestipol)
Prevalite® (cholestyramine)
Welchol® (colesevelam)

Fibric Acid Derivatives
Fenofibrate generics
Lopid® (gemfibrozil)

Antihyperlipidemics (continued)

HoFH Agents
Kynamro® (mipomersen)

Hypertriglyceridemia Agents
Lovaza® (omega-3 acid ethyl esters)

Statins
Lipitor® (atorvastatin)
Lovastatin generics
Mevacor® (lovastatin)
Pravachol® (pravastatin)
Zocor® (simvastatin)

Anti-Infectives

Antiherpes Virus Agents
Zovirax® (acyclovir)
***oral dosage forms only**

Hepatitis C Protease Inhibitors
Incivek® (telaprevir)
Victrelis® (boceprevir)

Inhaled Tobramycin Products
Bethkis® (tobramycin)
Tobi® (tobramycin)

Biologics

Adult Rheumatoid Arthritis
**Clinical PA may be required*
Enbrel® (etanercept)
Humira® (adalimumab)

Ankylosing Spondylitis
**Clinical PA may be required*
Enbrel® (etanercept)
Humira® (adalimumab)

Crohn's Disease
**Clinical PA may be required*
Humira® (adalimumab)

Juvenile Idiopathic Arthritis
**Clinical PA may be required*
Enbrel® (etanercept)
Humira® (adalimumab)

Plaque Psoriasis
**Clinical PA may be required*
Enbrel® (etanercept)
Humira® (adalimumab)

Psoriatic Arthritis
**Clinical PA may be required*
Enbrel® (etanercept)
Humira® (adalimumab)

Ulcerative Colitis
**Clinical PA may be required*
Humira® (adalimumab)

Cardiovascular Agents

ACE Inhibitors
Accupril® (quinapril)
Capoten® (captopril)
Lotensin® (benazepril)
Monopril® (fosinopril)
Prinivil® (lisinopril)
Vasotec® (enalapril)
Zestril® (lisinopril)

ACE Inhibitors/CCB Combos
Lotrel® (benzapril/amlodipine)

ARB/CCB Combos
Exforge® (amlodipine/valsartan)
Twynsta® (amlodipine/telmisartan)

Cardiovascular Agents (continued)

ARBs
Benicar® (olmesartan)
Benicar® HCT (olmesartan/HCTZ)
Cozaar® (losartan)
Diovan® (valsartan)
Diovan® HCT (valsartan/HCTZ)
Hyzaar® (losartan/HCTZ)
Micardis® (telmisartan)
Micardis® HCT (telmisartan/HCTZ)

Beta-Blockers
Coreg® (carvedilol)
Inderal® (propranolol)
Lopressor® (metoprolol tartrate)
Propranolol® Intensol (propranolol)
Tenormin® (atenolol)
Toprol® XL (metoprolol succinate)

CCBs (Dihydropyridines)
Adalat CC® (nifedipine ER)
Cardene® (nicardipine IR)
Norvasc® (amlodipine)
Procardia® XL (nifedipine ER)

CCBs (Non-Dihydropyridines)
Calan® (verapamil IR)
Calan® SR (verapamil SR)
Cardizem® (diltiazem IR)
Covera HS® (verapamil)
***branded products only**
Diltia XT® (diltiazem)
***brand & AB-rated generics**
Isoptin® SR (verapamil SR)
Tiazac® (diltiazem)
***brand & AB-rated generics**
Verelan® (verapamil SR)

Central Nervous System Agents

Adjunct Antiepileptics
Gabitril® (tiagabine)
Keppra® (levetiracetam)
Keppra® XR (levetiracetam XR)
Lyrica® (pregabalin)
Neurontin® (gabapentin)
Zonegran® (zonisamide)

Non-Benzo Sedative Hypnotics
Ambien® (zolpidem)
Zolpidem generics

Non-Scheduled Sleep Agents
Rozerem® (remelteon)

Diabetic Agents

Alphaglucosidase Inhibitors
Glyset® (miglitol)

Biguanides
Glucophage® (metformin)
Metformin ER generics

Dipeptidyl Peptidase-4 Inhibitors
Januvia® (sitagliptin)
Onglyza® (saxagliptin)

Incretin Mimetics
**Clinical PA may be required*
Byetta® (exenatide)
Victoza® (liraglutide)

Insulin Delivery Systems
All multi-dose vials
Novolog® PenFill & FlexPen
Novolog® Mix PenFill & FlexPen

The list of preferred drugs is continued on page 4. This list was updated on **9/1/2014**. Please visit the KDHE-DHCF Web site for the most current version. Please note that when a generic product is available for a preferred or non-preferred agent, the pharmacy will receive a lower reimbursement rate for the branded product unless a DAW PA is approved.

Preferred Drug List

Continued from page 3.

Diabetic Agents (continued)

Long-Acting Insulin (Vials Only)
Lantus® (insulin glargine)
Levemir® (insulin detemir)

Meglitinides
Prandin® (repaglinide)
Starlix® (nateglinide)

2nd Generation Sulfonylureas
Amaryl® (glimepiride)
DiaBeta® (glyburide)
Glucotrol® (glipizide)
Glucotrol® XL (glipizide XL)
Glucovance® (glyburide/metformin)
Glynase PresTab® (micronized glyburide)
Micronase® (glyburide)

SGLT2 Inhibitors
Farxiga® (dapagliflozin)
Invokana® (canagliflozin)

Thiazolidinediones
Actos® (pioglitazone)
ACTOplus Met® (pioglitazone/metformin)
ACTOplus Met® XR (pioglitazone/metformin)
Avandia® (rosiglitazone)

Gastrointestinal Agents

H_2 Antagonists
Pepcid® (famotidine)
Zantac® (ranitidine)

Oral Mesalamine Products
Delzicol® (mesalamine DR)
Pentasa® (mesalamine ER)

Pancreatic Enzyme Replacements
Creon® (pancrelipase)
Ultresa® (pancrelipase)
Viokace® (pancrelipase)
Zenpep® (pancrelipase)

Proton Pump Inhibitors
AcipHex® (rabeprazole)
Prilosec® (omeprazole)
Protonix® (pantoprazole)

Serotonin $5HT_3$ Antagonists
Zofran® (ondansetron)
Zofran® ODT (ondansetron)

Gout Agents

Xanthine Oxidase Inhibitors
Zyloprim® (allopurinol)

Injectables

Erythropoiesis-Stimulating Agents
Aranesp® (darbepoetin alfa)
Epogen® (epoetin alfa)
Procrit® (epoetin alfa)

Injectables (continued)

Growth Hormones
**Clinical PA may be required*
Genotropin® (somatropin)
Genotropin® MiniQuick (somatropin)
Norditropin® (somatropin)
Norditropin® FlexPro (somatropin)
Norditropin® Nordiflex (somatropin)
Omnitrope® (somatropin)

Ophthalmic Agents

Carbonic Anhydrase Inhibitors
Azopt® (brinzolamide)
Trusopt® (dorzolamide)

Ophthalmic Prostaglandin Analogs
Travatan Z® (travoprost)
Xalatan® (latanoprost)
Zioptan® (tafluprost)

Osteoporosis Agents

Bisphosphonates
Fosamax® (alendronate)
Fosamax Plus D® (alendronate/cholecalciferol)

Urologic Agents

Anticholinergic Agents
Ditropan® (oxybutynin)
Ditropan XL® (oxybutynin ER)
Toviaz® (fesoterodine)
Vesicare® (solifenacin)

Beta-3 Adrenergic Agonists
Myrbetriq® (mirabegron)

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